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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,897	06/30/2001	Elazar Rabani	Enz-60	1538

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ENZO BIOCHEM, INC.
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NEW YORK, NY 10022

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/896,897

Applicant(s)

RABANI ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/7/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 7/22/2004 has been entered. Claims 1-40 are pending.

Information Disclosure Statement

1. The documents 0104620 and 0104460 lined through in PTO-1449 filed 1/7/2004 were not signed because the documents were not found.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 2 is vague and indefinite because of the phrase "derived from". Since the phrase "derived from" is used to describe a chemically modified compound, it is unclear whether or not the analyte from a biological source is chemically modified. Clarification is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4, 7, 11, 13-15, 17-24, 27, 33-35 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Li (6,696,256).

Li discloses that a hybridization array is for use in identifying a plurality of different activated transcription factors in a biological sample (See column 5, lines 4-21). The biological sample is derived from a sample of cells (See column 10, lines 52-55). The transcription factor probes are attached to different fluorescent dye (See column 17, lines 60-67). The method of Li et al. involves using a hybridization array to hybridize to the transcription factor probe (See column 19, lines 7-16). The detectable marker can be chemiluminescent avidin or antibodies (See column 13, lines 50-67 and column 14, lines 1-9). Thus, each element used in the array of Li anticipates the limitations of claims as discussed above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5-6, 8-10, 12, 16, 25-26, 28-32, and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (6,696,256) as applied to claims 1-4, 7, 11, 13-15, 17-24, 27, 33-35 and 37 above, and further in view of Kool et al. (6,479,650, issued November 12, 2002).

The teachings of Li are set forth in section 4 above. Li does not disclose modified sugar or phosphate or base moieties, solid support and PNA.

Kool et al. disclose a combinatorial flurophore array library comprising nucleoside analogs attached to one or more solid support (See the Abstract). The oligonucleotide analogs comprising one or more of the subject nucleoside analogs have a modification to the sugar-phosphate base and have peptide nucleic acid (PNA) (See column 4, lines 56-62). The solid supports include polyacrylamid or pore glass (See column 18, lines 61-67). There is a spacer molecule (It is considered to a linker or linker arm) between solid support and nucleoside analog (See column 19, lines 12-15).

One of ordinary skill in the art would have been motivated to apply the modification to the sugar-phosphate base, PNA, the solid supports and the spacer molecule used as linker arm of Kool et al. to the array of Li. The motivation is that the array of Kool et al. is to be used in

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detecting a target nucleic acid in a sample (See column 4, lines 3-9) and the nucleoside analog used in the array improves fluorescence characteristics, increasing the range of emission wavelengths in which it is useful in biophysical and diagnostics applications (See column 2, lines 1-3). It would have been prima facie obvious to apply the modification to the sugar-phosphate base, PNA, the solid supports and the spacer molecule used as linker arm of Kool et al. to make the composition comprising the library of analytes, and array of nucleic acid in which the nucleic acid is fixed on a solid support and the analytes comprise UDT and UDE.

Summary

8. No claims are allowable.

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9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung JT
August 30, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/1/04